

510(k) Summary

Trade Name: SPY® Fluorescent Imaging System SEP - 7 2007
Model Number: SP2000
Common Name: Fluorescent Angiographic System
Classification: 21 CFR 892.1600
Product Code: 90 IZI
Classification: Class II
Manufacturer: Novadaq Technologies Inc.
2585 Skymark Avenue
Suite 306
Mississauga, Ontario
Canada
L4W 4L5
905.629.3822 ext. 240
Contact Name: Allison Manners
Vice President – Regulatory and Clinical Affairs

Date 510(k) Summary Prepared: July 29, 2007

Legally Marketed Predicate Devices:

The Novadaq® SPY Fluorescent Imaging System (SPY System) had received FDA 510(k) clearance for market in January 2005 (K#042961), subsequent 510(k), clearance for a labeling change in May 2006 (K#060867), clearance for use in plastic, micro- and reconstructive surgery in January 2007 (K063345), and clearance use of an alternative brand of fluorescent dye in coronary artery bypass surgery in May 2007, pending drug approval (K#071037).

The Leica FL800 had received FDA 510(k) clearance for market in September 2006 (K#061871). The Leica FL800 is intended for use to allow neurosurgeons to view blood flow.

Device Description:

The SPY Fluorescent Imaging System is currently cleared for use:

- For intra-operative visual assessment of the coronary vasculature and bypass grafts during coronary artery bypass graft (CABG) surgery.
- As an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

The Novadaq® Technologies SPY® Fluorescent Imaging System consists of 2 components:

- the SP2000 Imaging Device
- the SPY Paq®

The SPY Paqs are available in 2 configurations dependent on the manufacturer of the indocyanine green (ICG)¹:

- Five (5) procedure SPY Paq
- Six (6) procedure SPY Paq

Each SPY Paq contains sufficient numbers of custom sterile drapes, called Novadrape® and ICG and diluent for the noted number of imaging procedures. Each configuration of SPY Paq has a unique part number assigned to it, and different Instructions for Use exist for the SPY Paqs that contain the 2 brands of ICG. The different Instructions for Use also have unique part numbers for ease of assembly of the Paqs and guidance for the end user.

The SP2000 Imaging Device

The SP2000 Imaging Device consists of an imaging head containing a charge coupled device (CCD) camera, a laser light source, motion sensor and distance sensor attached via an articulating arm to a mobile cart. The mobile cart contains a flat panel display, computer, electronics enclosure and printer.

The SPY® System provides the surgeon with the capability to view record and replay fluorescent images of blood flow in vessels and bypass grafts of the heart. A laser light source is used to illuminate the area of interest.

¹ Novadaq provides the ICG as it is sold by the manufacturer and does not adulterate the integrity of the original packaging or labeling. IC-Green™ (Akorn, Inc.) is packaged in an IC-Green kit that contains 6 x 25 mg vials of ICG along with 6 x 10 ml ampules of Aqueous Solvent. Two IC-Green packages comprise the 6 procedure SPY Paq, since two vials of IC-Green are required for each imaging procedure. ICG-PULSION® is packaged with 5 x 25 mg vials of ICG. Two ICG PULSION packages constitute a 5 procedure SPY Paq. Sufficient quantities of Novadrapes are placed in each configuration.

ICG is injected intravenously through the central or peripheral venous line, bypass pump, cardioplegia line and coronary graft and while it is passing through the vessels, the absorption of laser light causes excitation of the dye followed by emission of infrared energy. The result is a fluorescent image of blood flow and related tissue perfusion in the vessels. A CCD camera captures the image. These images are used to evaluate the integrity of the coronary vasculature and blood flow in the heart and bypass grafts.

There have been no significant changes or modifications made to the SP2000 Imaging device since the original 510(k) clearance in January 2005 premarket notification 510(k) K#042961, the 510(k) submitted for a label change for this device K#060867, the clearance for use in the plastic, micro- and reconstructive surgery K063345, and clearance for use of an alternative brand of fluorescent dye – ICG PULSION® – in coronary artery bypass surgery in May 2007, pending drug approval K#071037.

This 510(k) submission describes a proposed change for the use of another brand of ICG and does not alter in any way the devices fundamental scientific technology or characteristics or the Indications for Use.

Intended Use of the SPY System:

The SPY Fluorescent Imaging System is indicated for use:

- As an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

Testing:

Animal studies, human experience and *in vitro* testing were conducted to support the safe and effective use of the SPY System in its original premarket notification 510(k) application (K042961).

The information contained within this Special premarket notification 510(k) demonstrates the equivalence of IC-Green™ and ICG-PULSION ICG products when used with the SPY Intra-operative Imaging Device.

In Vitro Testing:

Testing of the SPY® System was completed in conformance with the following standards. The SPY System successfully met all of the requirements for these standards.

1. Electrical per IEC 60601-1 and UL2601-1
2. Electromagnetic Compatibility per IEC 60601-1-2
3. Light Emitting Laser Products per 21 CFR 1040
4. Safe Use of Lasers in Health Care Facilities per ANSI Z136.3
5. American National Standard for Safe Use of Lasers per ANSI Z136.1

In Vivo Testing:

The SPY System is commercially available in the United States of America, Japan, Europe and Canada. To date, the SPY System has been used in over 4000 CABG procedures in humans and there have been no reports of adverse acute or long-term cellular, renal or hepatic effects. Along with the data from intra-operative imaging in CABG surgery, the use of the SPY System in plastic, micro- or reconstructive and other vascular surgery demonstrated the clinical utility of the device in producing high quality and resolution images of the entire vascular bed of the point of interest.

Results from the use of the SPY System has been the subject of 12 peer reviewed journal articles, 10 related to its use in cardiac surgery and 2 related to its use in transplantation surgeries, namely kidney and liver. Please refer to the bibliography in Section 19 - Clinical for a listing of all relevant journal articles.

The literature reports that the SPY System was able to non-invasively, quickly and safely identify 17 conduits in 311 patients that required revision during the surgical procedures. In all cases the lack of patency was visualized clearly by the SPY System using doses of ICG well below that approved for human use, allowing the surgeon to revise the graft thus decreasing subsequent myocardial infarctions and the morbidity and mortality associated with poor graft patency. Cardiac, renal and hepatic function were monitored during use of the SPY System and there were no reported adverse effects. These publications originated in Europe, Japan and Canada, where various brands of ICG are commercially available and used.

To support the original traditional 510(k) premarket notification application, the system was used in six pig studies. These studies demonstrated that:

- 1) it was possible to acquire high quality images in a simple and reproducible manner using small doses of ICG well below the concentrations approved for human use;
- 2) it was possible to perform multiple imaging sequences with no detrimental effects on heart function, coronary flow or peripheral pressure; and
- 3) it was possible to acquire images with no increase in myocardial tissue temperature; and
- 4) it was possible to visualize all of the coronary beds with high quality images even when the heart was in a vertical position for visualizing posterior arteries.

Therefore, in totality, the *in vivo* evidence shows that:

1. The exposure for the SPY® System is 35 mW/cm² which is far below the maximum permissible exposure of 327 mW/cm² established by ANSI for exposure to the skin.
2. Use of the SPY System does not cause any thermal damage to the area of interest, even after repeated imaging sequences.
3. For the heart, there were no changes in electrocardiograms or arterial pressures during and/or following SPY use.
4. There were no acute or long-term cellular effects of using the SPY System.
5. There were no acute or long-term renal or hepatic effects of using the SPY System.
6. The SPY System was able to acquire high quality images of the entire vascular bed on each area of interest.
7. The SPY System is capable of imaging through the skin to provide a visual assessment of dermal and subdermal blood flow.

Conclusions:

The above testing demonstrates that the SPY Intra-operative Imaging System is safe and effective in capturing and viewing fluorescent images for the visual assessment of blood flow indicative of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures, irrespective of the brand of ICG used, and is equivalent to the predicate devices.

Basu, Sankar

From: Allison Manners [amanners@novadaq.com]
Sent: Monday, August 27, 2007 5:36 PM
To: Basu, Sankar
Cc: Lukasz Brzozowski
Subject: Revisions for Special 510(k) K072222
Importance: High
Attachments: 3 - Indications for Use.doc; 4 - 510(k) Summary.doc

Dear Dr. Basu,

I have just faxed to you the documents as discussed in our telephone conversation this afternoon. In addition, for ease of your review, please find attached the electronic copies of the revised Indications for Use and the 510(k) Summary.

I trust that the information is acceptable, but please do not hesitate to contact me immediately should you require additional information.

Yours truly,
Allison Manners
VP, Regulatory and Clinical Affairs
Novadaq Technologies Inc.
Tel: (905) 629-3822 Ext. 240
Cell: (416) 567-5176



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Novadaq Technologies, Inc.
% Ms. Allison Manners
VP, Regulatory and Clinical Affairs
2585 Skymark Avenue, Suite 306
Mississauga, Ontario, Canada L4W 4L5

SEP - 7 2007

Re: K072222

Trade/Device Name: SPY® Fluorescent Imaging System: SP2000 Imaging Device
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: August 8, 2007
Received: August 10, 2007

Dear Ms. Manners:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may not market this device, however, until such time as the new drug application for the drug indocyanine green (ICG) manufactured by PULSION® is approved for human use by The Center for Drug Evaluation and Research, FDA. When the device is marketed, it will be subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

However, you are responsible to determine that the medical devices you use as components in the SPY® have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the Act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments.

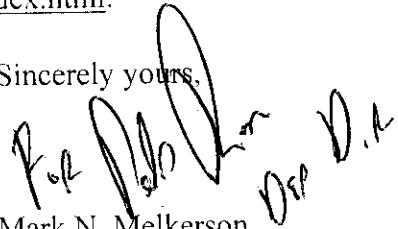
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification subject to approval of the indocyanine green (ICG) manufactured by PULSION® Medical Systems. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

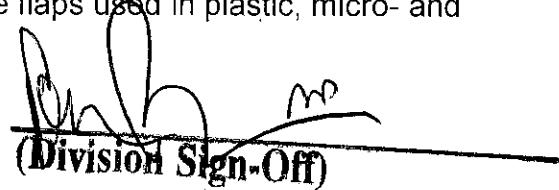

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K072222

Device Name: SPY® Fluorescent Imaging System: SP2000 Imaging Device

Indications for Use: The SPY System is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.



(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number 16072222

Prescription Use X Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)